OMB NO. 0990-0115

SOLICITATION

SECTION A – SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended

2. Request For Proposals (RFP) Number:	2. Issue Date:	3. Just in Time:	5. Set Aside:
NIH-NIAMS-BAA-02-05	February 14, 2002	___ NO _X_ YES See Part IV, Section L	_X_ NO ___ YES

6. TITLE: Pilot and Feasibility Trials for Osteoporosis

7. ISSUED BY:
National Institutes of Health
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Contracts Management Branch
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
Bethesda, Maryland 20892-6500

8. SUBMIT OFFERORS TO:
The address noted in Item #7 to the left
(Also see instructions under Packaging and Delivery of Proposals, page 24).

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the location specified above, and in the number of copies specified in Section L.1., GENERAL INFORMATION, paragraph (a), until **4:30 p.m. (local time), May 1, 2002**. Offers must be valid for 120 days. Please specify this period on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043." If your proposal is not received by the Contracting Officer or his/her designee at the place and by the time specified above, then it will be considered late and handled in accordance with HHSAR Clause 352.215-70, entitled "LATE PROPOSALS AND REVISIONS," located in SECTION L.1., paragraph (n) of this solicitation.

10. Offeror must provide full name, address, TIN, and if different, the address to which payment should be mailed. In addition, the Offeror must provide an electronic address (e-mail), along with a facsimile address.

11. FOR INFORMATION CALL: Elizabeth Shanahan, Contracting Officer
PHONE: 301-594-2543
E-MAIL: shanahae@mail.nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.

12. Table of Contents on following page.

NOTE: Offerors are responsible for routinely checking both the FedBizOpps website and the NIAMS Contracts Management Branch's website. Solicitation amendments, if any, will be posted at the FedBiz Opps website (http://www.fedbizopps.gov) and the NIAMS Contracts Management Branch's web site (http://www.niams.nih.gov/rtac/funding/grants/rfp/wwwrfp.htm). Individual notifications will not be provided.

DETAILED TABLE OF CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE AS SET FORTH IN SECTIONS B THROUGH H HEREIN CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE ANTICIPATED TERMS AND CONDITIONS OF ANY RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objectives of this initiative are to: 1) Identify and begin clinical testing of potential bone active agents, 2) Perform initial dosing trials and select appropriate populations and endpoints for larger scale testing in appropriately powered clinical intervention trials.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer for: 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT No. 1, attached hereto and made a part of this solicitation.

ARTICLE C.2. REPORTING REQUIREMENTS

a. PERFORMANCE AND TECHNICAL PROGRESS REPORTS

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The Contractor shall prepare and deliver the following reports in the manner stated below and in accordance with **ARTICLE F.2., DELIVERIES** of this contract:

1. **Monthly Recruitment/Enrollment Reports:**

   During Phase II, these reports shall be due by the 5th day of each month. The Contractor shall submit a table report which delineates the number of patients screened and enrolled during the reporting period. Included with this report shall be a report outlining the inclusion of women and minorities in the research study. The Contractor shall deliver these reports electronically as hypertext, Microsoft Word, or Corel WordPerfect documents to both the Project Officer and the Contracting Officer.

2. **Quarterly Performance Reports:**

   By the 5th day of the month following the quarter, and at other times as needed, the Contractor shall prepare brief interim Performance Reports to monitor study progress, quality of data, clinical investigator performance (enrollment, protocol compliance, drop out rate, forms completion, etc.), complications and adverse events. The

Contractor shall deliver these reports electronically as hypertext, Microsoft Word, or Corel WordPerfect documents to both the Project Officer and the Contracting Officer.

3. **Annual Progress Reports:**

By the 10th day of the month, the Contractor shall submit a report describing the activities during the reporting period and the activities planned for the ensuing reporting period. The initial report shall be submitted for the first full 12 months of the contract performance including any fractional part of the initial month. As a minimum, this report shall include the following: a) A qualitative description of overall progress; b) An indication of any current problems, which may impede performance, and proposed corrective action; c) A discussion of the work to be performed during the next reporting period; and d) Recommendations. The Contractor shall deliver these reports electronically as hypertext, Microsoft Word, or Corel WordPerfect documents to both the Project Officer and the Contracting Officer.

4. **Inclusion Enrollment Report:**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. This information shall be submitted in the format indicated in the attachment entitled "Inclusion Enrollment Report," which is set forth in Section J of the contract. This format, modified to indicate that it is a final report, shall also be used for reporting purposes in the final report. The report shall be submitted in accordance with ARTICLE F.1., DELIVERIES of this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001, applies. If this contract is for Phase III clinical trials, see II.B. of these guidelines. The Guidelines may be found at the following website:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

A description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups shall be included in the clinical trial protocol and the results of the subset analyses must be reported in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. Inclusion of the results of subset analyses is strongly encouraged in all publication submissions.

The Contractor shall deliver these reports electronically as hypertext, Microsoft Word, or Corel WordPerfect documents to both the Project Officer and the Contracting Officer.

5. **Final Report:**

The Final Report shall include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. A Final Report shall be submitted in accordance with Section F, Deliveries or Performance, of the contract. The Contractor shall deliver these reports electronically as hypertext, Microsoft Word, or Corel WordPerfect documents to both the Project Officer and the Contracting Officer.

6. **Other Reports:**

Optional Form 310, Protection of Human Subjects Assurance/Certification/Declaration: This form or its equivalent shall be submitted to the Contracting Officer to document the Contractor's/subcontractor's Institutional Review Board annual evaluation of the project, or in the event they have reviewed and approved changes to the study protocol or consent forms. This requirement applies to the prime Contractor, as well as the subcontractors.

Contract Financial Reports: Financial reports to include line item costs and effort expenditure reporting shall be required to be submitted to the Contracting Officer. If the contract is awarded to an organization that has an approved Letter of Credit, financial reports on Form NIH 2706 shall be submitted by the Contractor on a quarterly basis.

7. **Distribution of Reports:**

   The Contractor shall send copies of each report as specified below:

   Project Officer – 1 copy Contracting Officer – 1 copy

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR CLAUSE 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301/435-1986). In addition, one copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted within 90 days after contract expiration to the following address:

Contracting Officer
National Institutes of Health
National Institute on Neurological Disorders and Stroke
6001 Executive Boulevard, Suite 3287, MSC 9531
Bethesda, Maryland 20892-9531

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

a. All report deliverables required under this contract shall be packaged, marked, and delivered in accordance with the contract. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

b. Packaging

   1. For the purpose of reports, "immediately usable and acceptable condition" includes securing the pages together in a suitable and reasonable manner to be agreed upon by the Contractor and the NIAMS Project Officer.

   2. Boxes and/or other types of outer packaging, i.e., containers, wraps, etc., shall be suitable to the type of items being transmitted; and the mode of transportation utilized shall assure that such materials be received in an acceptable condition.

c. Marking

   All reports and/or other deliverable items under this contract shall be marked on the cover and cover page with the following identifiers.

   1. Project Title: "Pilot and Feasibility Trials for Osteoporosis"
   2. Contract Number:
   3. Name of Contractor:
   4. Name of Principal Investigator:

d. Shipping

Shipping shall be accomplished by reasonable and suitable means to be mutually agreed upon by the Contractor and the NIAMS Project Officer.

e. See SECTION F for delivery information.

SECTION E - INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

a. The Contracting Officer or a duly authorized representative shall perform inspection and acceptance of all deliverables and services to be provided.

b. For the purpose of this ARTICLE, the NIAMS Project Officer designated in ARTICLE G.2. is the authorized representative of the Contracting Officer.

c. Inspection and acceptance of contract work/deliverables shall be performed at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH, Bethesda, Maryland 20892. Inspection and acceptance shall be performed using progress reports, other required reports, and the final report. Site visits will also be employed for this purpose. Acceptance of work and/or report deliverables may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within thirty (30) days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:
52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (Short Form) (APRIL 1984)

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF CONTRACT

The period of this contract is _____ to _____. All work under this contract shall be completed by _____.

ARTICLE F.2. DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in ARTICLE C.1. and delivery and acceptance by the Contracting Officer, or duly authorized representative, of the items specified below. The report deliverables shall be delivered F.O.B. Destination, as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), in accordance with the stated delivery schedule.

Item	Description	Quantity	Delivery Schedule
1.	Monthly Recruitment/Enrollment Reports	1 – P.O. 1 – C.O.	Schedule will be included in the resultant contract.
2.	Quarterly Performance Reports	1 – P.O. 1 – C.O.	Schedule will be included in the resultant contract.
3.	Annual Progress Reports	1 – P.O. 1 – C.O.	Schedule will be included in the resultant contract.

4.	Inclusion Enrollment Report	1 – P.O. 1 – C.O.	Schedule will be included in the resultant contract.
5.	Final Report and Summary of Salient Results	2 – P.O. 1 – C.O.	On or before the last day of the contract.
6.	Optional Form 310, Protection of Human Subjects Assurance/Certification/Declar.	1 – P.O. 1 – C.O.	Schedule will be included in the resultant contract.

b. The above reports shall be addressed and delivered to:

[The specific information will be included in the resultant contract]

ARTICLE F.3. STOP WORK ORDER

This contract incorporates the following clause by reference with the same force and effect as if it were given in its full text. Upon request, the Contracting Officer shall make the full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:
52.242-15, STOP WORK ORDER (AUGUST 1989) WITH ALTERNATE I (APRIL 1984)

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. KEY PERSONNEL

Pursuant to the Key Personnel Clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

[To be specified prior to award]

The clause cited above contains a requirement for review and approval by the Contracting Officer of written request for change of Key Personnel reasonably in advance of diverting any of these individuals from the contract. The period of time for advance notice shall not be less than thirty (30) days.

ARTICLE G.2. PROJECT OFFICER

The following Project Officer will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance, and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH (RC)-4, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper payment" request, pursuant to FAR 32.9. These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

1. Invoice/financing requests shall be submitted as follows:

An original and two copies to the following designated billing office:

Contracting Officer
National Institutes of Health
National Institute of Neurological Disorders and Stroke
NeuroScience Center, Room 3287
6001 Executive Boulevard, MSC 9531
Bethesda, MD 20892-9531

2. Inquiries regarding payment of invoices/financing requests should be directed to the designated billing office, (301) 496-1813.

21. The Contractor agrees to provide with each invoice/financing request a detailed breakdown of the direct labor/personnel costs which shall include: (1) a list of the individuals by name; (2) their title/position under the contract; (3) the number of hours/percent of effort worked during the current period and the cumulative over the life of the contract; and (4) amount claimed for each individual for the current period as well as the cumulative since the inception of the contract.

4. The Contractor shall include the following certification on every invoice/contract financing request for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.7. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. [cite the applicable Public Law Number for the applicable Fiscal Year as stated in ARTICLE H._.] and ARTICLE H._. of the above referenced contract."

OR

ARTICLE G.3. ADVANCE PAYMENT INFORMATION

a. Advance payments will be provided under Letter of Credit Number _____, in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

The contractor shall withdraw funds pursuant to Department of Treasury Circular 1075 (31 CFR Part 205, http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html).

1. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH (RC)-1, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" payment request, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted as follows:

An original and two copies of the completion and/or final invoice shall be submitted to the following designated billing office:

Contracting Officer
National Institutes of Health
National Institute of Neurological Disorders and Stroke
Neuroscience Center, Room 3287
6001 Executive Boulevard, MSC 9531
Bethesda, MD 20892-9531

2. Inquiries regarding payments should be directed to the following office administering advance payments:

Division of Payment Management
11400 Rockville Pike
Rockwall Building #1, Suite 700
Rockville, MD 20852
(http://www.dpm.psc.gov/support/contact)

ARTICLE G.4. CONTRACT FINANCIAL REPORT *(will be included in any contract with organizations paid under the Payment Management System)*

a. Financial reports on the attached Form NIH-2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the instructions which accompany the form, in an original and two copies, not later than the thirtieth (30) working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph (e) below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH-2706 instructions entitled "**Preparation Instructions**," all columns A through J shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the *FIRST FULL THREE CALENDAR MONTHS* following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports shall be submitted on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

c. The following are examples of expenditure categories which may be reported:

Expenditure Category Percentage of Effort/Hours

1. Direct Labor *(List individuals by name, title/position, level of effort and amount claimed)*
2. Fringe Benefits *(Cite rate, base and amount)*
3. Consultants *(Identify individuals and amounts)*
4. Subcontracts *(Identify subcontractor by name and attach subcontractor invoices)*
5. Materials and Supplies
6. Accountable Personal Property/Equipment *(Identify equipment purchased on form HHS 565 and submit with the invoice)*
7. Other Direct Costs
8. Total Direct Costs
9. Indirect Costs/Overhead *(Cite rate, base and amount)*
10. General and Administrative Costs *(if applicable, cite rate, base and amount)*
11. Total Costs
12. Fixed Fee *(If applicable)*
13. Total Costs [Plus Fixed Fee]

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.5. INDIRECT COST RATES ***(will be included in any contract if the successful offeror is a profit making organization)***

In accordance with Federal Acquisition Regulation (FAR)(48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 Executive Boulevard, MSC 7540
Bethesda, MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, Contractor's Guide for Control of Government Property, (1990).

ARTICLE G.7. POST AWARD EVALUATION OF PAST PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation will be prepared during the contract term to assess ongoing performance.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (Commercials Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H.2. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the Institutional Review Board, Data Safety Monitoring Board (if applicable), and the NIAMS Project Officer. Written notice of such approval will be provided by the Contracting Officer. The Contractor shall submit to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310.

(NOTE TO OFFERORS: PRIOR APPROVAL FROM OPHR, HHS, MUST BE OBTAINED BEFORE AWARDING TO A CONTRACTOR NOT COVERED BY AN APPROPRIATE ASSURANCE OF COMPLIANCE, SEE SECTION L FOR MORE INFORMATION.)

ARTICLE H.3. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.4. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.5. DATA SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-0038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract. Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan. The Data Safety Monitoring Board and Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

   Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**
   [Applicable information to be included at award]

   [*NOTE: For FY 2002, the Public Law and Section No. are P.L. 107-116, Section 510]*

ARTICLE H.7. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**
   [Applicable information to be included at award]

   [NOTE: For FY 2002, the Public Law and Section No. are P.L. 107-116, Section 505]

ARTICLE H.8. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish and agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties. The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as Attachment No. 4.

ARTICLE H.9. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The Contractor agrees to comply with the Information Technology system security and/or privacy specifications set forth in the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, “Security of Federal Automated Information Systems,” and the DHHS Automated Information Systems,” and the DHHS Automated Information Systems Security Program Handbook (Release 2.0 dated May, 1994). The Contractor further agrees to include this provision in any subcontract awarded pursuant to this prime contract.

ARTICLE H.10. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (APRIL 1984):

> Pursuant to the provisions of paragraph (c) of the CONFIDENTIALITY OF INFORMATION clause incorporated in this contract (see SECTION I), the identity of subjects participating in various studies/protocols is considered confidential information. Identity of subjects shall include name, identifying number or symbol, or any other identifying particular as may be assigned to an individual.

ARTICLE H.11. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.12. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

b.	**Public Law No.**	**Fiscal Year**	**Dollar Amount of Salary Limitation***
	107-116	FY-02	Executive Level I*

*For contract expenditures using FY-02 funds, for the period 10/1/01 – 12/31/01, the Executive Level I rate is $161,200. Effective 1/1/02, for contract expenditures using FY-02 funds, the Executive Level I rate is increased to $166,700, and will remain at that level until such time as it is determined to raise the Executive Schedule annual rates. See the Web site listed below for the Executive Schedule rates of pay:

> For FY-02 Executive Level Salaries: http://www.opm.gov/oca/02tables/ex.pdf

c. Direct salaries which will be paid with FY-02 funds are limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

ARTICLE H.13. PUBLICATION AND PUBLICITY

The Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, under Contract No._____."

ARTICLE H.14. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph (b) below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be

financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. **Public Law No. and Section No** **Fiscal Year** **Period Covered**
[Applicable information to be included at award]

[NOTE: For FY 2002, the Public Law and Section No. are P.L. 107-116, Section 507]

ARTICLE H.15. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence on fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.16. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause:

a. Service Involving the Use of Information Technology

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

ARTICLE H.17. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated _____, is attached hereto and made a part of this contract.

2. The failure of any Contractor or Subcontractor to comply in good faith with FAR clause 52.219-8, entitled "UTILIZATION OF SMALL BUSINESS CONCERNS", incorporated in this contract, and with the attached SUBCONTRACTING PLAN will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16, entitled "LIQUIDATED DAMAGES - SUBCONTRACTING PLAN".

b. Subcontracting Reports

1. The Contractor shall submit the original and one (1) copy of the Subcontracting Report for Individual Contracts, SF-294, in accordance with the instructions on the report, as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, this report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

This report shall be sent to the following address:

Contracting Officer
Contracts Management Branch, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
Bethesda, Maryland 20892-6500

2. The Contractor shall submit one (1) copy of the Summary Subcontracting Report, SF-295, in accordance with the instructions on the report, as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   October 30th

   The first report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. This report shall be mailed to the following address:

   Office of Small and Disadvantaged Business Utilization
   Department of Health and Human Services
   Hubert H. Humphrey Building, Room 517-D
   200 Independence Avenue, S.W.
   Washington, D.C. 20201

3. The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 205-6475 for the correct address if unknown.

ARTICLE H.18. ANTI-LOBBYING [This applies to only Hospitals and State, Local and Indian Tribal Governments.]

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. Public Law No. and Section No | Fiscal Year | Period Covered

   [Applicable information to be included at award]

   [NOTE: FY 2002 Public Law and Section Nos. are P.L. 107-116, Section 503(a) & 503(b) for paragraphs a & b, respectively].

ARTICLE H.19. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L. 105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/. The standards applicable to this requirement will be determined during negotiations.

ARTICLE H.20. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://ott.od.nih.gov/NewPages/64FR72090.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms "research tools," "research materials," and "research resources" are used interchangeable and have the same meaning.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

SPECIAL NOTE FOR SOLICITATION PURPOSES: This SECTION I uses, as an example, clauses appropriate for the award of a cost-reimbursement research and development type contract. Any resultant contract shall include the clauses applicable to the selected offeror's organization and the type of contract awarded. Any additional clauses required by Public Law, Executive Order, or acquisition regulation in effect at the time of award shall be included in this SECTION I.

A listing of clauses appropriate for the award of other types of contracts will be provided upon request to the Contracting Officer/Contract Specialist identified in the cover letter of this Request for Proposals.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the contracting officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Reg	Clause	Date	Clause Title
FAR	52.202-1	Dec 2001	Definitions
FAR	52.203-3	Apr 1984	Gratuities (Over $100,000)
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
FAR	52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
FAR	52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
FAR	52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
FAR	52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data

Reg	Clause	Date	Clause Title
FAR	52.215-12	Oct 1997	Subcontractor Cost or Pricing Data ($Over $500,000)
FAR	52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
FAR	52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
FAR	52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
FAR	52.216-7	Mar 2000	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
FAR	52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
FAR	52.222-3	Aug 1996	Convict Labor
FAR	52.222-26	Feb 1999	Equal Opportunity
FAR	52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Dec 2001	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Oct 2000	Toxic Chemical Release Reporting
FAR	52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
FAR	52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
FAR	52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
FAR	52.227-14	Jun 1987	Rights in Data - General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	Jun 1996	Interest (Over $100,000)
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	May 2001	Prompt Payment
FAR	52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
FAR	52.233-1	Dec 1998	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy (Over $100,000)

Reg	Clause	Date	Clause Title
FAR	52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
FAR	52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
FAR	52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
FAR	52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
FAR	52.249-6	Sept 1996	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGRULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT 1/2002]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS AND MODIFICATIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations. It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause 52.216-7, ALLOWABLE COST AND PAYMENT (MARCH 2000), is modified in paragraph (a) to delete the words "subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substitute "45 CFR part 74, Appendix E". *[Applies to Hospitals, including both profit and non-profit]*.

FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN, ALTERNATE II (OCTOBER 2000), is added.

FAR clause 52.232-20, LIMITATION OF COSTS, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefore.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/contractor shall be determined at the time of award. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER I) CLAUSES

FAR 52.219-4, Notice Of Price Evaluation Preference For HubZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference…..

[ ] Offeror elects to waive the evaluation preference."

FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (MAY 2001).

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 10% to the price of all offers, except--…"

Alternate I (OCTOBER 1998), FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (OCTOBER 1999).

FAR 52.227-14, Rights in Data - General (JUNE 1987)

ALTERNATE IV (JUNE 1987), FAR 52.227-14, Rights in Data – General (JUNE 1987) *[Applies to Colleges and Universities only]*.

ALTERNATE V (JUNE 1987), FAR 52.227-14, Rights in Data – General (JUNE 1987). Specific data items that are not subject to paragraph (j) include: NONE

[NOTE TO OFFERORS: One or several of the following clauses pertaining to Cost Accounting Standards may be included in the resultant contract:]

*** (USE IN NEGOTIATED CONTRACTS OVER $500,000 – FOR FULL CAS COVERAGE [EXCEPT Small Businesses, Educational Institutions and Foreign Contractors – SEE EXCEPTIONS AT 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201-1) ***

FAR 52.230-2, Cost Accounting Standards (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS OVER $500,000 BUT LESS THAN $25 MILLION, AND THE OFFEROR CERTIFIES THAT IT IS ELIGIBLE FOR AND ELECTS TO USE MODIFIED CAS COVERAGE, EXCEPT Small Businesses, Educational Institutions, and Foreign Contractors – SEE EXCEPTIONS AT 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDICTION], SUBPART 9903.201.1) ***

FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT ARE EXEMPT FROM CAS REQUIREMENTS SOLELY ON THE BASIS THAT THE CONTRACT IS TO BE AWARDED TO A UNITED KINDGOM CONTRACTOR AND IS TO BE PERFORMED SUBSTANTIALLY IN THE UNITED KINGDOM – SEE 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201-1(B)(2)) ***

FAR 52.230-4, Consistency in Cost Accounting Practices (AUGUST 1992).

*** (USE BELOW IN NEGOTIATED CONTRACTS AND SUBCONTRACTS AWARDED TO EDUCATIONAL INSTITUTIONS, WHEN THE CONTRACTOR OR SUBCONTRACT PRICE EXCEEDS $500,000, UNLESS THE CONTRACT IS EXEMPTED (SEE 48 CFR CHAPTER 99, 9903.201-1), THIS CONTRACT IS TO BE PERFORMED BY AN FFRDC (SEE 9903.201-2 (c)(5), OR THE PROVISION AT 9903.201-2(c)(6)(FAR APPENDIX B) APPLIES.) ***

FAR 52.203-5, Cost Accounting Standards – Educational Institution (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT CONTAIN EITHER THE FORMER FAR CLAUSE 52.230-2, 52,30-3, OR 52.230-5.) ***

FAR 52.230-6, Administration of Cost Accounting Standards (APRIL 1996).

FAR 52.239-1, Privacy and Security Standards (AUGUST 1996).

FAR 52.243-2, Changes – Cost Reimbursement (AUGUST 1987), Alternate V (APRIL 1984).

FAR 52.251-1, Government Supply Sources (APRIL 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION / PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR/PHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR 352.223-70, Safety and Health (JANUARY 2001)
HHSAR 352.224-70, Confidentiality of Information (APRIL 1984).
HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES

NIH (RC)-7 Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).
NIH (RC)-11, Research Patient Care Costs (APRIL 1984).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, Subcontracts for Commercial Items and Commercial Components (MAY 2001)

a. **Definition**.

Commercial item, as used in this clause, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, as used in this clause, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

b. To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

c. Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:

1. 52.219-8, Utilization of Small Business (15 U.S.C. 637(d)(2) and (3
2. 52.222-26, Equal Opportunity (E.O. 11246);
3. 52.222-35, Affirmative Action for Special Disabled and Vietnam Era Veterans (38 U.S.C. 4212(a));
4. 52.222-36, Affirmative Action for Handicapped Workers (29 U.S.C. 793); and
5. 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C. 1241)

d. The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this RFP:

1. Technical Objectives, 3 pages.

THE FOLLOWING FORM MUST BE COMPLETED AND SUBMITTED PRIOR TO THE SUBMISSOIN OF YOUR PROPOSAL BY NO LATER THAN APRIL 15, 2002.

2. Proposal Intent Response Sheet, March 1984, 1 page.

THE FOLLOWING FORMS MUST BE COMPLETED AND SUBMITTED WITH EACH TECHNICAL PROPOSAL: (A copy of each form shall be included with the original and every copy of the technical proposal).

3. Government Notice for Handling Proposals, 1 page.
4. Summary of Labor & Direct Costs (TECHNICAL PROPOSAL), 1 page.
5. Summary of Related Activities, March 1984, 1 page.
6. Targeted/Planned Enrollment Table, May 2001 (Mod. By OAMP 10/2001), 1 page.
7. Protection of Human Subjects Assurance Identification/Certification/Declaration, Optional Form 310, January 1995, 1 page.

THE FOLLOWING FORMS MUST BE COMPLETED AND SUBMITTED WITH EACH BUSINESS PROPOSAL:

8. NIH-2043, Proposal Summary and Data Record, June 1982, 2 pages.
9. Summary of Annual Costs (BUSINESS PROPOSAL), September 1992, 2 pages.
10. SF-LLL, Disclosure of Lobbying Activities, December 1989, 3 pages.
11. Small Business Subcontracting Plan Format, October 2000, 7 pages.
12. Small Disadvantaged Business (SDB) Participation Plan, 1 page.
13. Contact Points, July 1991, 1 page.

THE FOLLOWING FORMS WILL BE ATTACHED TO ANY CONTRACT RESULTING FROM THIS RFP: (They are included here for informational purposes only).

14. NIH (RC)-7, Procurement of Certain Equipment, (OMB Bulletin 81-16), April 1984, 1 page.
15. NIH (RC)-1, Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, May 1997, 4 pages.
16. NIH (RC)-11, Research Patient Care Costs, April 1984, 1 page.
17. NIH 2706, Financial Report of Individual Project/Contract, with instructions, May 1997, 3 pages.
18. Privacy Act System of Records, #09-25-0200, April 1997, 10 pages.
19. Safety and Health, HHSAR Clause 352.223-70, January 2001, 1 page.
20. Inclusion Enrollment Report, May 2001 (Mod. By OAMP 10/01), 1 page.

NOTE: Section K - Representations and Certifications - Negotiated Contracts must be completed, signed and included with the Business Proposal. It is available at URL: http://amb.nci.nih.gov/forms/rcneg.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

Representations and Certifications - Negotiated Contracts
This document must be accessed electronically from the INTERNET at the following URL:

http://amb.nci.nih.gov/forms/rcneg.pdf

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THESE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **PACKAGING AND DELIVERY OF PROPOSAL**

Your proposal shall be organized as specified in SECTION L.2., INSTRUCTIONS TO OFFERORS.

Proposals for furnishing the supplies and/or services in the SCHEDULE will be accepted at the location specified in (3) below, and in the number of copies specified in (1) below, until 4:30 p.m. (local time), **May 1, 2002**. Delivery and marking of proposals shall be as indicated below:

1. Number of Copies: The number of copies required of each part of your proposal are as follows:

   Technical Proposal: Original plus 10 copies
   Business Proposal: Original plus 4 copies

2. External Package Marking

   In addition to the address cited below, the outside of each package should be marked with the following information:

   RFP No. NIH-NIAMS-BAA-02-05

3. Address

   If mailing your proposal through the U.S. Postal Service or sent by an overnight delivery service (e.g., Federal Express, Airborne, DHL, etc.) or if the proposal is hand-delivered, your proposal must be delivered/sent to the following address:

   Contracts Management Branch
   National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
   Natcher Building, Room 5AS13A
   45 Center Drive, MSC 6500
   Bethesda, Maryland 20892-6500

b. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]**

(a) *Definitions*. As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

(End of Provision)

c. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

d. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

e. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

f. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that multiple awards will be made from this solicitation and that awards may be made on/about September 2002.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement type completion contract, with a term of three (3) years, and that incremental funding will be used for this contract **(see Section L.2. (c**) - Business Proposal Instructions.

g. **ESTIMATE OF EFFORT**

It is expected that a cost-reimbursement type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government estimates that the total cost (direct and indirect) will range from $300,000 to $500,000 per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

h. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition. Any other commitment, either explicit or implied, is invalid.

i. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

j. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

k. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that the most important award selection factor shall be the technical evaluation of proposals. The technical proposal will receive paramount consideration in the selection of the Contractor for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. The relative importance of the award selection factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the offeror whose proposal provides the best overall value to the Government, cost and other factors considered.

l. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

m. **SERVICE OF PROTEST - FAR 52.233-2 (AUGUST 1996)**

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Contracts Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
Bethesda, Maryland 20892-6500

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

n. **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a cost reimbursement type contract will be awarded. Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required

by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Section L1.a. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm (120 days minimum) and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and labor-categories, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated [See Attachment entitled, SUMMARY OF LABOR AND DIRECT COSTS (TECHNICAL PROPOSAL)]. However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified and separate cost estimates provided.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, SECTION M, of this RFP.

(7) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

a) Copies of the Department of Health and Human services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through interventions or interaction with the individual, or identifiable private information. The regulation extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1 – 6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of the research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are

in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, (telephone: 301-496-7014*), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR* an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/*

(10) Required Education in the Protection of Human Research Participants

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts. Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and//or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for the use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwattch.com/order/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and /or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

(11) Inclusion of Women and Minorities in Research Involving Human Subjects

It is the policy of the NIH that women and members of minority groups and their sub-population must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusions is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusions under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (section 492B of Public Law 103-43).

All investigator proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of clinical research adopted in June2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (http://www.nih.gov/news/crp/97report/execsum.htm).

These revisions relating to NIH defined Phase III clinical trials and require: a) all proposals and /or protocols to provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guide_amended_10_2001.htm, Definitions – Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences. The proposal must also include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and /or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include an analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support not negate significant differences in intervention effect between subgroups.

In addition, the proposal should contain a description of the proposal outreach programs for recruiting women and minorities as participants.

The form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table, " should be used when preparing your response to the solicitation requirements for inclusion of women and minorities.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report for Clinical Research Study Population (See Section J – List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," shall be in used for reporting in the resultant contract.

(12) Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethnical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (section 101 (b) and 410 (b) of 45 GFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offereor presents clear and convincing justification for an exclusion. In the technical proposal, the offereor should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from contact person listed in the RFP.

(13) Data and Safety Monitoring in Clinical Trials

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offferors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusion of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not-files/not98-084.html

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(14) Privacy Act – Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

-to the cognizant audit agency and the General Accounting Office for auditing.

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

-to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(15) Selection of Offerors

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review panel. The panel will evaluate each technical proposal in strict conformity with the technical evaluation criteria of the RFP, utilizing point scores and written critiques. The panel may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business proposal will be subjected to a cost realism and/or cost/price analysis.

c) If award is made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government has communication and/or conducts discussions prior to awarding a contract-

(1) Based on the written recommendations of the technical review committee/peer review group/source evaluation panel, the Contracting Officer will, in concert with program staff, establish an ORDER OF MERIT RANKING. This ranking will be based upon the scientific merit of the proposed research, the relevance to the technical objectives outlined in this solicitation, and program/scientific priority.

Oral or written discussions will be conducted with offerors whose proposals are the most meritorious, relevant, and of highest priority to the program area. All aspects of the proposal are subject to discussion, including cost, technical approach, and contractual terms and conditions. At the conclusion of discussions, each offeror still being considered for awards hall be given an opportunity to submit a written Final Proposal Revisions (FPR) with the reservation of the right to conduct limited negations to finalize details of the award with the selected source in accordance with HHSAR 315.670.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, evaluation of cost and any and all other award selection factors specified in Section M.

f) The NIAMS reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAMS' requirements. Synopses of awards exceeding $25,000 will be published on the FedBizOpps website.

(16) Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 8 to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6)The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(17) HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(18) Extent of Small Disadvantaged Business Participation

In accordance with FAR part 15.304(c)4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under Section M shall be used for evaluating SDB participation under this RFP. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment must clearly stated in your proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size/NAICS-cover-page.htm. The Department of Commerce website for the annual determination is: http://www.arnet.gov/References/sdbadjustments.htm.

Offerors shall **provide in one clearly marked section of the Business Proposal,** SDB participation targets, expressed as dollars and percentages of total contract value, in each authorized NAICS Industry Subsector(s), as may be applicable. The applicable NAICS Code for this requirement is 541710, as specified in Section L.1 (d). A total target for SDB participation by the prime contractor, including joint ventures and team arrangements*, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **SDB Participation Plan information may be provided in one the format prescribed in Section J, attachment entitled Small Disadvantaged Business (SDB) Participation Plan, or in a format developed by the offeror.**

If the SDB evaluation factor in Section M includes a subfactor that considers the extent to which SDB concerns must be specifically identified in the participation plan, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute for submission of the subcontracting plan**, if it is required by this solicitation.

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(19) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(20) Salary Rate Limitation in Fiscal Year 2002

Offerors are advised that pursuant to P.L. 107-116 no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses), also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health and the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of the Executive Level I."

Information regarding the FY-2002 rate can be found at: http://www.opm.gov/oca/02tables/ex.pdf .

(21) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

(1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

(3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

i) public disclosure of significant financial interests;
ii) monitoring of research by independent reviewers;
iii) modification of the research plan;
iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
v) divestiture of significant financial interests; or
vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(22) ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) the either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions the have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining toe students (who are 17 years of age or older) enrolled at the covered educational entity.

(23) Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating produce development. Intellectual property restrictions can stifle the broad dissemination of the new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the p [public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH0funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf .

(24) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L. 105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR Part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

(25) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

(a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991)

(b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

(c) Facilities Capital Cost of Money, FAR Clause 52.215-16 (October 1997)

(d) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8 (October 1997)

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks. **Please note that there is a page limitation of 30 pages for the Technical Proposal (see item (2) Technical Proposal Table of Contents/Format below).**

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

1) Objectives/ Specific Aims. State clearly and concisely the overall goals and specific aims of the proposed project. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere.

2) Background and Significance. Review pertinent already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it. Describe the scientific rationale for the selection of the targeted therapy selected. Indicate the significance of the proposed study to advance current approaches for the evaluation of the selected therapy and relation to comparable work in progress elsewhere. Discuss the innovative technological and conceptual aspects of this project.

3) Technical Approach. Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Describe the technical approach corresponding to each of the Technical Objectives/Specific Aims presented in TECHNICAL DISCUSSIONS, paragraph a, Statement of Work, subparagraph 1., Objectives/Specific Aims. Include a description of preliminary data, if available. Discuss the scientific rationale, feasibility, expected results and alternatives for each of the approaches selected. Include description of statistical approaches when appropriate. If the study involves human subjects, include a description of the plan to include women, minorities, and children in the study population. When collaborative approaches with existing organizations and networks are proposed, include letters of commitment.

4) Methods. Describe the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

5) Schedule. Provide a schedule for completion of the work and delivery of items specified in the Statement of Work or Article F.2., Deliveries, Part I, Schedule. Performance or delivery schedules should be indicated for phases or segments, as applicable, as well as for the overall program. Schedules should be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

i) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

ii) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss their qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

iii) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity must be indicated and the anticipated sources must be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

iv) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

v) Summary of Related Activities

Offerors must complete the Summary of Related Activities form included as Attachment 5. This form should indicate all other support for the principal investigator/project director (and other key personnel named in the proposal) in direct support of their research endeavors. Other support is defined as any project specific funds or resources, whether Federal, non-Federal or institutional, available to the principal investigator/project director (and other key personnel named in the proposal) in direct support of their research endeavors through research or training grants, cooperative agreements, contracts, fellowships, gifts, prizes, and other means. For prizes and gifts, include only those that support the specific project.

Information regarding active or pending sources of support available to the principal investigator/project director (and other key personnel named in the proposal), whether related to this proposal or not, is an important part of the review and award process and must be included in the proposal. Please follow carefully the instructions on the Summary of Related Activities attachment in providing this information.

vi) Institutional Experience and Facilities

Describe organizational and administrative structure of the proposed program and institutional commitment to the program.

Describe the facilities and resources, plans for study coordination, data management and analysis, as well as the availability of computers and other equipment for performance of the proposed project.

(2) **Technical Proposal Table of Contents/Format**

(NOTE: Instructions to offerors are included in parentheses or as footnotes.)

a. Technical Proposal Cover Sheet…….……Page 1

b. Technical Proposal Table of Contents ……..….Page 2

c. Summary of Objectives and Methods (Abstract)*……..Page 3

d. Lay Language Summary…….Page 4

e. Technical Plan (Refer to Technical Proposal Instructions indicated above).

It is recommended that the Technical Plan section be limited to only 30 pages, excluding references. Also, see notes indicated with asterisks below.

(1) SCOPE OF WORK
   (a) Objectives/Specific Aims……Page 5
   (b) Background and Significance …….Page
   (c) Technical Approach ……Page
   (d) Methods ……..Page
   (e) Schedule ……..Page

(2) PERSONNEL (List by name, title, department and organization, and detail each person's qualifications and role in the project).

   Provide narrative for:

   (a) Principal Investigator/Project Director
   (b) Other Investigators
   (c) Additional Personnel (e.g., technical support, subcontractors, consultants)

   {NOTE: For key personnel, include 2 page biosketch/resume and the form entitled "Summary of Related Activities" included in Part III, Section J, Attachment 5.]

(3) FACILITIES/RESOURCES and DIRECT COSTS (List Describe all equipment, facilities and other resources available for this project; and floor plan of laboratory/clinical space).

(4) OTHER CONSIDERATIONS (Provide brief narrative of any unique arrangements, safety procedures in place, human subject and minority and gender issues, animal welfare issues, etc.).

f. OTHER SUPPORT (A Summary of Related Activities" for must be provided for all Key Personnel; this form is located in PART III, Section J, Attachment 5).

g. HUMAN SUBJECTS AND MINORITY AND GENDER ISSUES NOTOTHERWISE ADDRESSED (If applicable)

h. Data Safety Monitoring

i. (Located in Part III, Section J, Attachment 4.

j. Literature Cited

k. Appendices (protocol, policy manuals, etc., for above Technical Plan; list each Appendix; Appendices must be clear and legible and easily located.)

* State the proposal's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving these goals. DO NOT EXCEED ONE PAGE in providing the abstract. Identify the RFP Number, institution, and Principal Investigator on the abstract.

**The front side of a page equals one page. The front and back of a page equals two pages.

***Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch.

(3) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M).

(4) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(5) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(6) **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems" and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May 1994). The proposal will also need to include similar information for any subcontract proposed.
NOTE: OMB A-130 is accessible via web site:
http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

c. <u>BUSINESS PROPOSAL INSTRUCTIONS</u>

(1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee and profit.

(2) **Cost and Pricing Data**

****This document is INCLUDED in the "Just in Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.****

1. **General Instructions**

A. You must provide the following information shall be provided on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of Offeror;
(3) Name and telephone number of point of contact;
(4) Name, address, and telephone number of Contract Administration Office, (if available);
(5) Name, address, and telephone number of Audit Office (if available);
(6) Type of contract action (that is, new contract, change order, price revision/redermination, letter contract, unpriced order, or other);
(7) Proposed cost and/or price; profit or fee (as applicable); and total;
(8) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(9) Whether your organization is subject to cost accounting standards; whether you organization has submitted CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(10) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, the offeror, if selected for discussions, grants the Contracting Officer and authorized representatives the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(11) Date of submission; and
(12) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including—

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as possible after the final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4, priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the Contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth at FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing the source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier data agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly quarterly, yearly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other** Costs. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, patient care/test costs, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties.** If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours (see Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties, if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

(3) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may

require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include—

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(4) **Total Compensation Plan - Instructions**

*******This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP. *******

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN THE COMPETITIVE RANGE WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(5) **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(6) **Qualifications of the Offeror**

a) You are requested to submit a summary of your General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts.

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process. **Past Performance information (see Section L.2.a.18 of this RFP) must be submitted with the Business Proposal.**

(7) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and(j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

a. It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

b. The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

(End of Provision)

f) **FAR 52.215-16, Facilities Capital Cost of Money (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires that the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

__ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

__ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(8) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(9) **Proposer's Annual Financial Report**

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(10) **Representations and Certifications**

One copy of the Representations and Certifications shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. The Representations and Certifications are available at the following URL: **http://amb.nci.nih.gov/forms/rcneg.pdf**

(11) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

***** This document is INCLUDED in the "Just In Tine" procedures. Specific instructions for this submission of this document are outlines in SECTION L.1.a. of this RFP. *****

All offerors included in the competitive range will be required to submit a copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

A. GENERAL INFORMATION REGARDING EVALUATION FACTORS FOR AWARD

The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. The technical evaluation is more important than cost and price, and cost and price is more important than the Extent of Small Disadvantaged Business Participation Plan (SDB) factor. All evaluation factors other than cost or price, when combined are significantly more important than cost or price. In any event, the Government reserves the right to make an award to that offeror(s) whose proposal provides the best overall value to the Government. The trade-off process described in FAR 15.101-1 shall be employed.

An initial technical review will be conducted to evaluate technical proposals against the technical evaluation criteria specified below. Offerors must submit sufficient information to allow evaluation of their proposals based on the research objectives and the technical evaluation criteria listed below. Failure to provide any of the information required to evaluate the proposal may result in less than a favorable evaluation. Offerors are advised to pay particular attention to providing the information requested in the NOTES TO OFFERORS included in the Technical Objectives (Section J, Attachment 1) in order to assist the reviewers in evaluation proposals.

All technical proposal will undergo initial evaluation by a peer review group also known as the Source Evaluation Panel (SEP). The final stage of the evaluation is the establishment of an Order of Merit Ranking in which all competing proposals are ranked on the basis of their respective technical relevance and scientific merit. Subsequent awards depend upon the availability of funds, scientific priority, and program balance that the NIAMS determines to exist at the time of the award selection.

The evaluation of cost and the extent of SDB participation will not be conducted on any proposal determined to be "technically unacceptable," or on any proposal not deemed to be one of the most highly rated technical proposals based on the initial technical review.

The estimated cost of a proposal must be reasonable for the work to be performed. The business proposal will be subjected to a cost realism and/or cost analysis.

If a proposal is received from a foreign source, the technical review group will address the need or appropriateness of accomplishing the work outside the United States.

B. HUMAN SUBJECTS

This research project involves human subjects. NIH Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan, or provide sufficient information on the research subjects to allow a determination by NIAMS that a designated exemption is appropriate.

If concerns are identified and discussion are held with your organization, you will be afforded the opportunity to further discuss and/or clarify your position during discussions and in your Final Proposal Revision (FPR). If, after discussions, concerns still exist, your proposal may not be considered further for award.

(b) **Data Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include

procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work/Technical Objectives for the solicitation specific requirements for data and safety monitoring.

The NIAMS will evaluate the acceptability of the proposed Data and Safety Monitoring Plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis.

If the information provided about data and safety monitoring is determined to be inadequate and discussions are held with your organization, you will be afforded the opportunity to further discuss and/or clarify your plan during discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is considered inadequate, your proposal may not be considered further for award.

(c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for Phase III clinical trials, it is required that all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to address differences in intervention effect (see NIH Guide: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. Definitions – Significant Difference) by sex/gender and/or racial/ethnic groups, including relevant subpopulations, if applicable, unless the Government has specified in the Statement of Work/Technical Objectives that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

The proposal must also address the proposed outreach programs for recruiting women and minorities as participants.

Where you, as the offeror determine that inclusion of women and minority populations is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAMS will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

If the rationale is not considered acceptable by the Government and discussions are held with your organization, you will be afforded the opportunity to further discuss, clarify, or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

(d) **Children**

Children (i.e., individuals under the age of 21) must be included in all human subject research unless there are scientific and ethical reasons not be include them. The offeror's proposal must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. If the offeror determines that exclusion of a specific age range of children is appropriate, the proposal must address the rationale for such exclusion.

If the information about the inclusion of children is absent or considered inadequate and discussions are held with your organization, you will be afforded the opportunity to further discuss, clarify, or modify your plan for

inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

C. **TECHNICAL EVALUATION CRITERIA**

Technical proposals shall be evaluated in accordance with the following technical evaluation criteria which are listed and weighted in the order of their relative importance. The maximum total score possible is 100 points. **Proposals will be judged solely on the written material provided by the offeror.**

1. **SIGNIFICANCE AND INNOVATION.....30**
   a. The significance of the proposed study to advance the therapy of the disease. Does this study address an important problem? If the aims of the trial are achieved, will available therapeutic options and scientific knowledge about the disease be advanced? What will be the effect of these studies on the concepts or methods that drive this field? (20 POINTS)
   b. Does the project employ novel concepts, approaches or methods? Does the project challenge existing paradigms or develop new methodologies or technologies? (10 POINTS)

2. **TECHNICAL MERIT.....35**
   a. The scientific and medical rationale for the selection of the approach and patient population. (15 POINTS)
   b. The documented adequacy, feasibility, scientific and technical merit of the proposed methods and approaches (include inclusion/exclusion criteria, selection of outcome measures, selection of dose/duration of treatment, and other components of the protocol itemized in the Research and Technical Objectives section) to meet the research objectives under the Technical Objective. (10 POINTS)
   c. Suitability of the proposed plan for randomization of patients, sample size calculation, data management and data analysis plan. (5 POINTS)
   d. Adequacy of the proposed methods of coordination, monitoring, and central management of all activities required by the study protocol, including procedures, coordination of data collection, and specialized tests. (5 POINTS)

3. **PERSONNEL AND EXPERIENCE.....25**
   a. Documented training, experience, expertise, and availability of the Principal Investigator necessary for planning and directing the proposed studies. (15 POINTS)
   b. Documented training, experience, and availability of all personnel in conducting the proposed technical procedures. (10 POINTS)

4. **INSTITUTIONAL EXPERIENCE AND FACILITIES.....10**
   a. Adequacy of the organizational and administrative structure of the proposed program and program and institutional commitment to the program. (5 POINTS)
   b. Availability and adequacy of the facilities and resources necessary for conducting study coordination, data management and analysis, including computer hardware, software and other equipment in order to successfully implement the requirements of the contract.
   (5 POINTS)

D. **SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR**

SDB participation will not be scored, but the Government's conclusion about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

Evaluation of the SDB Participation Plan will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(1) Extent of commitment to use SDB concerns in performance of the contract (in terms of dollars and percentage of total contract value); and

(2) The complexity and variety of work to be performed by SDB concerns.

F. PAST PERFORMANCE EVALUATION

Past performance is not considered to be appropriate for evaluation in this acquisition. Because of the innovative nature of work required by the RFP, the FAR requirements for evaluating an offeror's past performance information is waived for this project. Past performance, however, will be considered when determining Contractor responsibility using the information required by the "Qualifications of the Offeror" portion of SECTION L of the solicitation.

TECHNICAL OBJECTIVES
REQUEST FOR PROPOSALS (RFP) NO. NIH-NIAMS-BAA-02-05
PILOT AND FEASIBILITY TRIALS IN OSTEOPOROSIS

A. Background

The National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS) supports research aimed at discovering the causes of bone diseases and developing new treatments for the prevention and cure of these diseases. Numerous new therapeutic approaches are now feasible because of exciting developments in the basic science of bone.

The purpose of this Broad Agency Announcement (BAA) is to solicit proposals for small, pilot, and feasibility clinical trials and to encourage the adequate testing of novel and innovative potential therapies for osteoporosis. Projects supported would be phase I/phase II human trials to test basic safety and efficacy of treatments that would not be otherwise developed and pursued by private industry.

The objectives of this initiative are to: 1) Identify and begin clinical testing of potential bone active agents; and 2) Perform initial dosing trials and select appropriate populations and endpoints for larger scale testing in appropriately powered clinical intervention trials.

To achieve the main goal of this BAA, NIAMS seeks to support small, pilot and feasibility trials. The trials should be designed so that the preliminary data obtained would be sufficient to design the next phase (for example, Phase II/III), for which the investigators will have to seek separate funding or obtain evidence of efficacy where a large, double-blind, placebo-controlled trial is not feasible.

NIAMS expects to foster collaborations and partnerships between academia and biotechnology and pharmaceutical companies through the development and conduct of these clinical trials. Some of the biologicals, drugs, devices, and other products and agents to be tested may have been under research and development in the biotechnology and pharmaceutical companies. Collaborative arrangements are thus encouraged under this solicitation.

B. TECHNICAL OBJECTIVES

To design, develop and carry out pilot/feasibility (Phase I/II) clinical studies to establish the safety and gather enough preliminary evidence of efficacy of new and innovative therapeutic/prevention strategies for osteoporosis.

[NOTES TO OFFERORS:

1. *Offerors should design, develop and implement a clinical trial protocol to test the safety/efficacy of new therapeutics for osteoporosis. The approach is to be selected by the Offerors. The intervention may be intended to be used as a single treatment agent, as an adjuvant to existing therapies or as a combination therapy of known agents. The specific aims of the trial must be clearly and concisely presented. These should include a clear specification of the primary and major secondary endpoints to be measured with a clear differentiation of the importance of various endpoints.*
2. *The proposal should include a background and significance section that describes the scientific and medical rationale to test the selected approach, as well as a description of potential advantages and/or additional benefits to be obtained by the use of such a new approach. The significance of the proposed clinical trial, how the trial will test the hypothesis proposed and how the results will advance our knowledge of theory and practice in this area must be clearly stated.*
3. *Preliminary Studies. A summary of the studies that led to the proposed clinical trial should be presented. Data from pre-clinical studies, other applications/uses of the proposed approach and from pilot studies which show the need for such a trial or show the feasibility of the trial should also be presented if available. For feasibility studies, supporting data from other research should be included so that the approach chosen is clearly justified.*
4. *Draft Protocol. The proposal must include a draft protocol that meets the specific aims set by the Offeror for the clinical trial. The experimental design should describe the methodology to be used including:A plan overview and description of trial design (screening, baseline, number of visits, laboratory tests, etc).*

a) Plans to recruit and coordinate activities, training, reporting, etc. with other Clinical Centers, if a multicenter trial is proposed. The proposal shall include a description of strengths and capabilities, including expertise in relevant clinical studies, and participation in similar clinical trials for each Clinical Center. Letters of commitment and cooperation must be provided.

b) Overall recruitment strategies with a description of pitfalls, competing trials, and alternative options. NIH policy requires that women and members of minority groups and their subpopulations and children be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research (see Section L.2., paragraph (r), for further information and guidance).

c) Patient inclusion and exclusion criteria, and definitions of disease severity or other entry criteria.

d) Description of study agents including rationale for the selection of agent dose and duration of treatment. (Arrangements made with suppliers for obtaining the appropriate formulation of the agents should be described. FDA regulatory issues related to study agents may be handled during phase I of the trial. See timetable below).

e) Selection and discussion of instruments to measure primary and secondary outcomes.

f) Plans to monitor potential toxicities.

g) Copies of all available data collection forms, informed consent forms, study instruments and questionnaires, and a schedule of clinic visits and patient assessments.

h) Randomization strategy, if appropriate.

i) Sample size calculations, estimates of attrition, and rationale for the selection of methods to conduct analysis of endpoints. The technical proposal must include a description of sample calculation and detail the assumptions made.

j) *Plans to set up Safety and Data Monitoring for the trials. (Please don't name specific members to be proposed but only describe their expertise.)]*

C. **ESTIMATED TIMETABLE**:

It is anticipated that work will progress in phases as follows:

Phase I - Planning (4 - 6 months):
The planning stage includes the refinement of the protocol, as well as the development of the manual of operations, data forms, and training materials.

Phase II - Recruitment and Follow-up (7-24):
Subjects will be screened and recruited during this phase. Patients will be treated for at least a year

Phase III - Analysis (25-36 months):
Data collection and clean up will be completed. Data analyses will be performed and manuscript preparation will take place.

PROPOSAL INTENT RESPONSE SHEET

RFP No. NIH-NIAMS-BAA-02-05

PLEASE REVIEW THE ATTACHED REQUEST FOR PROPOSAL. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY **APRIL 1, 2002**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

==========

Company/Institution:

Company/Institution Address:

Principal Investigator Name and Title:

Telephone No. and Email Address:

Names of Collaborating Institutions and Investigators (including consultants and subcontractors):

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

==========

RETURN TO: National Institutes of Health
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Attention: Elizabeth Shanahan, Contracting Officer
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
BETHESDA, MD 20892-6500

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 352.215-1.

(f) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(g) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

(SUBMIT WITH TECHNICAL PROPOSAL)

SUMMARY OF LABOR AND DIRECT COSTS

COST ELEMENTS	YEAR 01	YEAR 02	YEAR 03	YEAR 04	TOTAL
DIRECT LABOR (List individuals by name / labor category. Indicate hours or % effort for each. _____ _____ _____ _____ _____ _____ _____					
TOTAL LABOR COSTS	$_____	$_____	$_____	$_____	$_____
MATERIALS/SUPPLIES (Specify items and cost for each.)	$_____	$_____	$_____	$_____	$_____
TRAVEL COSTS (Specify trips and costs.)	$_____	$_____	$_____	$_____	$_____
EQUIPMENT (List separately)	$_____	$_____	$_____	$_____	$_____
CONSULTANTS (Identify name & amount)	$_____	$_____	$_____	$_____	$_____
SUBCONTRACTS (Identify name & amount)	$_____	$_____	$_____	$_____	$_____
OTHER DIRECT COST (Specify items & costs for all elements)	$_____	$_____	$_____	$_____	$_____
TOTAL DIRECT COST	$_____	$_____	$_____	$_____	$_____

Specific Instructions:

1. Enter dollar totals for each person/labor category under Direct Labor. Hours or other effort estimates must be indicated.
2. DO NOT include salary rates under Direct Labor.
3. Total Labor Costs should include fringe benefit cost estimates in this total.
4. DO NOT include any Indirect Costs or Fixed-Fee.
5. DO NOT show the total proposal amount offered.
6. This form must be included with the TECHNICAL PROPOSAL.

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals* in this proposal.

Professional's Name and Title/Position: _____

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*If an individual has no obligation(s), so state.

b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*.

Professional's Name and Title/Position: _____

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*If no commitment of effort is intended, so state.

c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

Name	Title/Position	Total Proposed Effort
1.		
2.		
3.		
4.		

TARGETED/PLANNED ENROLLMENT TABLE

This report format should NOT be used for data collection study participants

Study Title:			
Total Planned Enrollment:			
TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total of All Subjects*			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects*			

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

OMB No. 9999-0020
OMB No.0925-0418
Approved for use through 12/31/97

PROTECTION OF HUMAN SUBJECTS
ASSURANCE IDENTIFICATION/CERTIFICATION/DECLARATION
(Common Federal Rule)

POLICY: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See Section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
ORIGINAL	GRANT CONTRACT FELLOWSHIP	
FOLLOW UP	COOPERATIVE AGREEMENT	
EXEMPTION	OTHER:	

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

This Assurance, on file with the Department of Health and Human Services, covers this activity:

Assurance Identification no. M— IRB identification no. _____

This Assurance, on file with *(agency/dept.)* _____, covers this activity.

Assurance Identification no. _____ IRB identification no. _____ *(if applicable)*

No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101 (b), paragraph

7. Certification of IRB Review *(Respond to one of the following IF you have an Assurance on file)*

This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on

(date) _____ by: Full IRB Review or Expedited Review.

This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution
11. Phone No. *(with area code)*	12. Fax No. *(with area code)*	
13. Name of Official		14. Title
15. Signature		16. Date

Authorized for local reproductionOPTIONAL FORM 310 (1-95)

Protection of Human Subjects Assurance Identification/Certification/Declaration

ATTACHMENT 7

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH **PROPOSAL SUMMARY AND DATA RECORD**	Solicitation/CONTRACT NUMBER
PROJECT TITLE (Title or Solicitation or Contract Proposal)	
LEGAL NAME AND ADDRESS OF OFFEROR	PLACE OF PERFORMANCE (Full address including ZIP)
TYPE OF CONTRACT PROPOSED □ COST-REIMBURSEMENT □ FIXED PRICE □ COST-PLUS-FIXED-FEE □ OTHER	
ESTIMATED TIME REQUIRED TO COMPLETE PROJECT	
ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget	PROPOSED STARTING DATE
DOES THIS PROPOSAL INCLUDE A SUBCONTRACT □ YES □ NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)	

NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS	□ YES □ NO
Institution's General Assurance re: Human Subjects	DATE APPROVED _____ □ PENDING
Institution's Review Board's Approval of this Proposal	DATE APPROVED _____ □ PENDING
An example of the informed consent for this study is enclosed	□ YES □ NO
A Clinical Protocol is enclosed	□ YES □ NO

OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE Solicitation (Use attachment if necessary)

ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY	NUMBER OF EMPLOYEES CURRENTLY EMPLOYED
	DOLLAR VOLUME OF BUSINESS PER ANNUM
	THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR	SIGNATURE OF BUSINESS REPRESENTATIVE
TYPED NAME AND TITLE	TYPED NAME AND TITLE
EMPLOYER IDENTIFICATION NUMBER	DATE OF OFFER

Provision of the Social Security Number is voluntary. Social Security Numbers are requested for the purpose of accurate and efficient identification, review, and management of NIH Extramural Programs. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.

(SUBMIT WITH BUSINESS PROPOSAL)

SUMMARY OF ANNUAL COSTS

COST ELEMENTS	YEAR 01	YEAR 02	YEAR 03	YEAR 04	TOTAL
DIRECT LABOR (List individuals by name / labor category. Indicate hours or % effort for each. _____ _____ _____ _____ _____ _____ _____					
TOTAL LABOR COSTS	$_____	$_____	$_____	$_____	$_____
MATERIALS/SUPPLIES (Specify items and cost for each.)	$_____	$_____	$_____	$_____	$_____
TRAVEL COSTS (Specify trips and costs.)	$_____	$_____	$_____	$_____	$_____
EQUIPMENT (List separately)	$_____	$_____	$_____	$_____	$_____
CONSULTANTS (Identify name & amount)	$_____	$_____	$_____	$_____	$_____
SUBCONTRACTS (Identify name & amount)	$_____	$_____	$_____	$_____	$_____
OTHER DIRECT COST (Specify items & costs for all elements)	$_____	$_____	$_____	$_____	$_____
TOTAL DIRECT COST	$_____	$_____	$_____	$_____	$_____
OVERHEAD (%)*	$_____	$_____	$_____	$_____	$_____
G&A EXPENSE (%)*	$_____	$_____	$_____	$_____	$_____
TOTAL EST. COST	$_____	$_____	$_____	$_____	$_____
AWARD FEE (maximum for Superior performance)	$_____	$_____	$_____	$_____	$_____
TOTAL COST PLUS AWARD FEE	$_____	$_____	$_____	$_____	$_____

Specific Instructions:

1. Enter dollar totals for each person/labor category under Direct Labor. Hours or other effort estimates must be indicated as well as salary/wage rates for each.
2. For * specify applicable base.
3. This form must be included with the BUSINESS PROPOSAL.

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action: a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	2. Status of Federal Action: a. bid/offer/application b. Initial award c. post-award	3. Report Type: a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity: ☐ Prime ☐ Subawardee Tier_____, if known: Congressional District, if known:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime Congressional District, if known:
6. Federal Department/Agency:	7. Federal Program Name/Description CFDA Number, if applicable: _____
8. Federal Action Number, if known:	9. Award Amount, if known: $
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): (attach Continuation Sheet(s)	a. Individual Performing Services (including address if different from No. 10a) (last name, first name, MI) SF-LLL-A, if necessary)
11. Amount of Payment (check all that apply): $_____ ☐ actual ☐ planned	13. Type of Payment (check all that apply): ☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____
12. Form of Payment (check all that apply): ☐ a. cash ☐ b. in-kind; specify: nature_____ value_____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for payment indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached:
Yes No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____Date: _____
Federal Use Only	Authorized for Local Reproduction Standard Form—LLL

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity:_____ Page _____ of _____

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing of attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (Solicitation) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "Solicitation-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN:_____

CONTRACTOR_____

ADDRESS: _____

_____

_____

DUNN & BRADSTREET NUMBER: _____

SOLICITATION OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

_____

TOTAL CONTRACT AMOUNT: $_____ $_____

Total contract or Base-Year, if options — Option #1 (if applicable)

$ _____ $_____ $ _____

Option #2 (if applicable) — Option #3 (if applicable) — Option #4 (if applicable)

TOTAL MODIFICATION AMOUNT, IF APPLICABLE $ _____

TOTAL TASK ORDER AMOUNT, IF APPLICABLE $ _____

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): _____

The following is a suggested model for use when developing subcontracting plans as required by Section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this model plan has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable; however, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. Further, the use of this model is not intended to waive other requirements that may be applicable under statute or regulation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

Subcontracting Plan
(Rev. October 2001)

1. Type of Plan (check one)

_____ Individual plan (all elements developed specifically for this contract and applicable for the full term of this contract).

_____ Master plan (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

_____ Commercial products/service plan, including goals, covers the offerer's fiscal year and applies to the entire production of commercial items or delivery of services sold by either the entire company or a portion thereof (e.g., division, plant, or product line); this includes planned subcontracting for both commercial and Government business.

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) Small Business, Veteran, (VOSB)Service-Disabled Veteran and "Other than small business" (other) as subcontractors, for the base year and each option year, as specified in FAR 19.704 (break out and append option year goals, if the contract contains option years) or project annual subcontracting base and goals under commercial plans.

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is $ _____ (b + g = a)

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOB, HUBZone, and VOSB): (% of "a") $ _____ and _____%

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") $ _____ and _____% Federal Subcontract Goal 5%

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") $ _____ and _____% Federal Subcontract Goal 5%

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") $ _____ and _____%

f. Total estimated dollar and percent of planned subcontracting with VETERAN SMALL BUSINESSES* (% of "a") $ _____ and _____% Federal Subcontracting Goal 3%

g. Total estimated dollar and percent of planned subcontracting with "OTHER" THAN SMALL BUSINESSES: (% of "a")
(% of "a") $ _____ and _____%

Notes: *Service-disaled veteran goal should be included as part of veteran small business goal.

1. Federal prime contract goals are:
   SB equals 23%; SDB equals 5%; HUBZone equals 2.5%; WOSB equals 5% and VOSB equals 3% and can serve as objectives for subcontracting goal development.

2. SDB, WOSB, HUBZone and VOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.

Provide a description of ALL the products and/or services, to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply).

Product/Service	Other	SB	SDB	WOSB	HUBZoneSB	VOSB

i. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone, and VOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, SDB, WOSB,HUBZone, and VOSB concerns were determined, how the capabilities of these concerns were considered for subcontract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

j. Indirect costs have ____ have not____ been included in the dollar and percentage subcontracting goals above (check one).

k. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, and VOSB concerns.

_____

_____

_____

3. **Program Administrator:**

NAME/TITLE:
ADDRESS:
TELEPHONE/E-MAIL:

Duties: Has general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans. Other duties include, but are not limited to, the following activities:

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, and VOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing.

b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, and VOSB concerns from all possible sources;

c. Ensuring periodic rotation of potential subcontractors on bidder's lists;

d. Ensuring that requests for contracts (RFC) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone and VOSB concerns;

e. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, and VOSB concerns to include the SBA's PRO-Net System, (http://www.sba.gov) the Federal Acquisition Computer Network (FACNET) Contractor Registration Database, the NIH E-Portals in Commerce (e-PIC), (http://epic.od.nih.gov/), National Minority Purchasing Council Vendor Information Service, the Office of

Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices;

f. Establishing and maintaining contract and subcontract award records;

g. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc;

h. Ensuring that SB, SDB, WOSB, HUBZone, and VOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;

i. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended;

j. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;

k. Preparing, and submitting timely, required subcontract reports;

k. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and

m. Other duties:_____

4. **Equitable Opportunity**

Describe efforts the offeror will make to ensure that SB, SDB, WOSB, HUBZone, and VOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

6) Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending SB, SDB, WOSB, HUBZone, and VOSB procurement conferences and trade fairs; 4) requesting sources from the Small Business Administrations (SBA) PRO-Net and SUB-Net Systems, (http://www.sba.gov/) and other SBA and Federal agency resources; and 5) Conducting market surveys to identify new sources, to include, accessing the NIH E-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/).

b. Internal efforts to guide and encourage purchasing personnel:

1) Conducting workshops, seminars, and training programs;
2) Establishing, maintaining, and utilizing SB, SDB, WOSB, HUBZone, and VOSB source lists, guides, and other data for soliciting subcontractors; and
3) Monitoring activities to evaluate compliance with the subcontracting plan.

c. Additional efforts: _____

5. **Flow Down Clause**

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $500,000 ($1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c).)

6. **Reporting and Cooperation**

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and attendant Optional Form 312, SDB Participation Report, if applicable, (required only for contracts containing the clause 52.219-25) and SF-295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 295.

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	SF-294/of 312	4/30
Apr 1 - Sept 30	SF-294/of 312	10/30
Oct 1 - Sept 30	SF-295	10/30

Special instructions for commercial products plan: SF295 Report is due on 10/30 each year for the previous fiscal year ending 9/30.

Report forms are posted at http://sbo.od.nih.gov under "Forms."

a. Submit SF-294 to cognizant Contracting Officer.

b. Submit Optional Form 312, (OF-312), if applicable, to cognizant Awarding Contracting Officer.

c. Submit SF-295 to cognizant Contracting Officer and to the:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
200 Independence Avenue, SW
Humphrey H. Building, Room 517-D
Washington, D.C. 20201

d. Submit "information" copy of the SF-295 and the SF-294 upon request to the SBA Commercial Market Representative (CMR); visit the SBA at http://www.sba.gov/gc and click on assistance directory to locate your nearest CMR.

7. **Record keeping**

The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

a. SB, SDB, WOSB, HUBZone, and VOSB source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, and VOSB sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone, and/or VOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards.

d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and

f. On a contract-by-contract basis, records to support subcontract award data including the name address, and business type and size of each subcontractor. (This item is not required for *contract – by – contract basis* for company or division-wide commercial products plans.)

g. Additional records: _____

SIGNATURE PAGE

(applies to Master or Commercial type plans)

This master or commercial type subcontracting plan is submitted by:

Contractor: _____

Contractor Signature: _____

Typed Name: _____

Title: _____

Date Prepared: _____

And Is Accepted By:

Agency:_____

Contracting Officer Signature:_____

Typed Name: _____

Date: _____

SMALL DISADVANTAGED BUSINESS (SDB) PARTICIPATION PLAN

1A. OFFEROR'S NAME	2. REQUEST FOR PROPOSAL (RFP) NUMBER
1B. OFFEROR'S ADDRESS	3. TOTAL SDB PARTICIPATION AT PRIME CONTRACT LEVEL

A. NAICS CODE	B. DOLLARS	C. PERCENT

4. TOTAL SDB PARTICIPATION AT SUBCONTRACT LEVEL

A. DOLLARS	B. PERCENT

5. SDB PARTICIPATION AT SUBCONTRACT LEVEL BY NAICS SUBSECTOR GROUP

A. NAICS SUBSECTOR GROUP	B. DOLLARS	C. PERCENT

INSTRUCTIONS

Item 3. Identify participation, if any, by SDB concerns at the prime contract level by dollar amount and percentage of total contract value. All prime contract dollars must be identified under the NAICS code assigned to the acquisition (see Section L2(a)(15) of the solicitation).

Item 4. Identify participation, if any, by SDB concerns at the subcontract level by dollar amount and percentage of total contract value.

Item 5. Identify, by NAICS Subsector Group, participation of SDB concerns at the subcontract level by dollar amount, and percentage of total contract value. (SDB concerns need not be identified by name.) See http://www.sba.gov/size/NAICS-cover-page.htm for descriptions of the NAICS Subsector Groups.

CONTACT POINTS

Complete the following and return with the BUSINESS PROPOSAL.

Name, Title and Address* of Business Representative with whom daily contact is required.

_____ _____
Name Telephone Number

_____ _____
Institutional Title FAX Number

_____ _____
Institutional Office E-Mail Address

_____
Institution Name

_____
**Street Address

_____
City, State Zip Code

Name, Institutional Title and Address of Proposed Principal Investigator

_____ _____
Name Telephone Number

_____ _____
Institutional Title FAX Number

_____ _____
Institutional Division, etc. E-Mail Address

_____
**Street Address

_____
City, State Zip Code

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

* May not necessarily be same as legal address of offeror.
**Please use actual street address, not P.O. Box.

PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the Contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting Officer.

67 - Photographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045 - ADP Supplies and Support Equipment.)
71 - Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Home-type Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Contractor and determined essential by the Contracting Officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost-reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letterhead or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission Clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the contracting officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (l) costs of a prior billing period, but not previously billed; or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval, which are not set forth in an Advance Understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) Number. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number:** Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared:** Insert the date the invoice/financing request is prepared.

(d) **Contract Number and Date:** Insert the contract number and the effective date of the contract.

(e) **Payee's Name and Address:** Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract:** Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Incurred Cost – Current:** Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.

(j) **Incurred Cost – Cumulative:** Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(l) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.

- The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule.

- Be preceded by an asterisk (*) if the equipment is below the approval level.

(4) **Materials and Supplies:** Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay** " List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract's Advance Understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed.

(9) **Other:** List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs—Overhead:** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned:** Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments:** Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) **Grand Totals**

The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE /FINANCING REQUEST

(a) Billing Office Name and Address: NATIONAL INSTITUTES OF HEALTH National Institute of Arthritis and Musculuskeletal And Skin Diseases Natcher Building, Room 5AS13A 45 CENTER DRIVE, MSC 6500 Bethesda, Maryland 20892-6500 (e) Payee's Name and Address ABC CORPORATION 100 Main Street Anywhere, U.S.A. zip code Attn: Name, Title & Phone Number of Official to Whom Payment is Sent	(b) Invoice/Financing Request Number: (c) Date Invoice Prepared: (d) Contract Number and Effective Date: (e) Total Estimated Cost of Contract: (f) Total Fixed Fee:
(h) This invoice/financing request represents reimbursable costs from August 1, 2000 through August 31, 2000	

		(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception
(k)	Direct Costs		
(l)	Direct Labor	$ 3,400	$ 6,800
(2)	Fringe Benefits	600	1,200
(3)	Accountable Personal Property (Attach Form HHS-565)		
	Permanent Research	3,000	6,000
	General Purpose	2,000	2,000
(4)	Materials and Supplies	2,000	4,000
(5)	Premium Pay	100	150
(6)	Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
(7)	Travel (Domestic)	200	200
	(Foreign)	200	200
(8)	Subcontract Costs	-0-	-0-
(9)	Other	-0-	-0-
	Total Direct Costs	$11,600	$20,650
(l)	Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(m)	Indirect Costs -- Overhead		
	_____% of Direct Labor or Other Base (Formula)	4,000	6,000
(n)	Fixed-Fee Earned (Formula)	700	1,400
(o)	Total Amount Claimed	$18,700	$31,650
(p)	Adjustments		
	Outstanding Suspensions		(1,700)
(q)	Grand Totals	$18,700	$29,950

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

_____ _____

Name of Official) (Title)

RESEARCH PATIENT CARE COSTS

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.
(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.
(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.
(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.
(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

INSTRUCTIONS FOR COMPLETING FORM NIH 2706
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by be NIH in monitoring the application of financial and personnel resources to the NIH contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the project officer.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on Form NIH 2706.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

National Institutes of Health Financial Report of Individual Project/Contract Complete this Form in Accordance with Accompanying Instructions	Project:	Contract No.	Date of Report:	OMB No. 0990-0134 0990-0131
	Performance Period: Reporting Period:	Contractor Name and Address:		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost-Current Period	Cumulative Cost to Date (D & E)	Estimated Cost to Complete	Estimated Cost At Completion (F & G)	Funded Contract Amount	Variance (Over or Under) (I - H)
	Funded	Actual							
A	B	C	D	E	F	G	H	I	J

NIH-2706 (5/92) (Formerly HHS-646)

PRIVACY ACT SYSTEM OF RECORDS

Federal Register: April 7, 1997 (Volume 62, Number 66)
Notices, Pages 16596_16602

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Privacy Act of 1974; New System of Records
agency: National Institutes of Health, HHS.
action: Notification of a new system of records.

Summary: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of a new system of records, 09_25_0200, ``Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This system notice serves as an umbrella system for most NIH clinical, epidemiologic and biometric research studies. Thirty-eight existing NIH system notices were subsumed under this notice (listed in the system notice under System Manager(s)), to reduce the number and avoid future proliferation of like system notices. We are also proposing routine uses for this new system; with two exceptions, these routine uses were already contained in the preceding system notices. The first new routine use will allow disclosure to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions. The purpose of the disclosure is to plan for or provide such services, bill or collect third-party reimbursements. The second new routine use will allow disclosure for the purpose of reporting child, elder, or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

Dates: NIH invites interested parties to submit comments on the proposed internal and routine uses on or before May 7, 1997. NIH has sent a report of a New System to the Congress and to the Office of Management and Budget (OMB) on November 6, 1996. This system of records will be effective 40 days from the date of publication unless NIH receives comments on the routine uses which would result in a contrary determination.

Address: Please submit comments to: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301- 496-2832.

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday. for further information contact: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496- 2832.

The numbers listed above are not toll free.

Supplementary information: The National Institutes of Health (NIH) proposes to establish a new system of records: 09-25-0200, ``Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This umbrella system of records will be used by NIH staff to document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities. This inclusive system notice will achieve agency administrative efficiencies, avoiding confusion created by the current fragmented pool of Institute, Center and Division (ICD) system notices. Because of its unique organizational structure, NIH has, over the recent decades, experienced a proliferation of almost identical system notices that differ only by disease/disorder under study or ICD interest. This system notice subsumes thirty-eight existing system notices and will offer coverage for research not currently covered by an appropriate system notice. The consolidation of similar research systems of records into one generic-type notice will also serve the public interest. It will alleviate burden on the public associated with multiple attempts at notification, access and correction of record information when individuals are not sure which research system notice applied to their study participation.

The system will comprise records about individuals as relevant to a articular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services

utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence. The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act Regulations. The System Manager will control access to the data. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are HHS employees, and contractors responsible for implementing the research.

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and videotapes. Manual and computerized records will be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, ``Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31). Data on computer files is accessed by keyword known only to authorized users. Access to information is thus limited to those with a need to know. Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Researchers authorized to conduct research on biological specimens will typically access to the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual. All authorized users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Depending upon the sensitivity of the information in the record, additional safeguard measures are employed.

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use permits disclosure of a record for an authorized research purpose under specified conditions. The second routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such disclosure would be made only pursuant to a request of the individual. The third routine use allows disclosure to the Department of Justice for use in litigation. The fourth routine use allows disclosure of records to contractor, grantee, experts, consultants or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. The fifth routine use allows disclosure to certain relevant third parties (e.g., relatives, prior employees, Motor Vehicle Administration, State vita statistics offices) when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. The sixth routine use allows disclosure to tumor registries for maintenance of health statistics. The seventh routine use allows the PHS to inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, or to disclose such information to State or local public health departments under specified circumstances. The eighth routine use allows disclosure of certain diseases and conditions, including infectious diseases, to appropriate representatives of State or Federal Government as required by State or Federal law. The ninth routine use allows records to be disclosed to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements. The tenth routine use allows disclosure to organizations deemed qualified by the Secretary, DHHS, to carry out quality assessment, medical audits or utilization reviews. The eleventh routine use allows information to be disclosed for the purpose of reporting child, elder or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective. Dated: October 30, 1996.
Anthony L. Itteilag,
Deputy Director for Management, National Institutes of Health. 09-25-0200

SYSTEM NAME:Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:None.

SYSTEM LOCATION: Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM: Adults and/or children who are the subjects of clinical, epidemiologic, and biometric research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: Normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM: The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM: ``Research and Investigation,'' ``Appointment and Authority of the Directors of the National Research Institutes,'' ``National Cancer Institute,'' ``National Eye Institute,'' ``National Heart, Lung and Blood Institute,'' ``National Institute on Aging,'' ``National Institute on Alcohol Abuse and Alcoholism,'' ``National Institute on Allergy and Infectious Diseases,'' ``National Institute of Arthritis and Musculoskeletal and Skin Diseases,'' ``National Institute of Child Health and Human Development,'' ``National Institute on Deafness and Other Communication Disorders,'' ``National Institute of Dental Research,'' ``National Institute of Diabetes, and Digestive and Kidney Diseases,'' ``National Institute of Drug Abuse,'' ``National Institute of Environmental Health Sciences,'' ``National Institute of Mental Health,'' ``National Institute of Neurological Disorders and Stroke,'' and the ``National Center for Human Genome Research,'' of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S) To document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the

health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a property identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social Security numbers, date of birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social Security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in epidemiologic studies.

7. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices. (b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE: Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and videotapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY: During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, Social Security Number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.
2. Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

4. Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the HHS General Administration Manual and Part 6, ``ADP System Security'' of the HHS ADP Systems Security Manual. RETENTION AND DISPOSAL: Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1--``Keeping and Destroying Records'' (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. William A. White Clinical Research Program medical records (Saint Elizabeths Hospital, NIMH) are retained for 5 years after last

discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30 years after discharge or death. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions. SYSTEM MANAGER(S) AND ADDRESS: See Appendix I for a listing of current system managers. This system is for use by all NIH Institutes, Centers, and Divisions. The following system notices have been subsumed under this umbrella system notice.
09-25-0001 Clinical Research: Patient Records, HHS/NIH/NHLBI
09-25-0010Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI
09-25-0015 Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS
09-25-0016 Clinical Research: Collaborative Perinatal Project, HHS/ NIH/NINDS
09-25-0026 Clinical Research: Nervous System Studies, HHS/NIH/NINDS
09-25-0028 Clinical Research: Patient Medical Histories, HHS/NIH/ NINDS and HHS/NIH/NIDCD 09-25-0031 Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS
09-25-0037Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA
09-25-0038Clinical Research: Patient Data, HHS/NIH/NIDDK
09-25-0039 Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK
09-25-0040 Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK
09-25-0042 Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR
09-25-0044 Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR
09-25-0046 Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID
09-25-0053 Clinical Research: Vision Studies, HHS/NIH/NEI
09-25-0057 Clinical Research: Burkitt's Lymphonma Registry, HHS/ NIH/NCI
09-25-0060 Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI
09-25-0067 Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI
09-25-0069 NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI
09-25-0074 Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI
09-25-0077 Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI
09-25-0126 Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI
09-25-0128 Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS
09-25-0129 Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/ NIDCD
09-25-0130 Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI
09-25-0134 Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS
09-25-0142 Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA
09-25-0143 Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID
09-25-0145 Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/ NEI
09-25-0148 Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0152 Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR
09-25-0153 Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/ NIH/NICHD
09-25-0154 Biomedical Research: Records of Subjects: 1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/ NCI; and 2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD
09-25-0170 Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK
09-25-0172 Clinical Research: National Center for Human Genome Research, HHS/NIH/NCHGR
09-25-0201 Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH

09-25-0205 Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/ NIMH
09-25-0212 Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH

NOTIFICATION PROCEDURE: To determine if a record exists, write to the appropriate ICD Privacy Act Coordinator listed below. In cases where the requestor knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: Individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requestor must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.
Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship. If the requester does not know which Institute, Center or Division Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address:

NIH Privacy Act Officer, Office of Management Assessment, Building 31, Room 1B05 31 Center Drive MSC 2075 Bethesda, MD 20892-2075. NIH Privacy Act Coordinators Office of the Director, (OD), NIH Associate Director for Disease Prevention, OD, NIH, Building 1, Room 260, 1 Center Drive Bethesda, MD 20892 National Cancer Institute (NCI)Privacy Act Coordinator, NCI, NIH Building 31, Room 10A34 31 Center Drive Bethesda, MD 20892 National Eye Institute (NEI) Privacy Act Coordinator, NEI, NIH Building 31, Room 6A-19 31 Center Drive Bethesda, MD 20892	National Heart, Lung and Blood Institute (NHLBI) Privacy Act Coordinator, NHLBI, NIH Building 31, Room 5A08 31 Center Drive Bethesda, MD 20892 National Institute of Allergy and Infectious Diseases (NIAID) Privacy Act Coordinator, NIAID, NIH Solar Building, Room 3C-23 6003 Executive Blvd. Bethesda, MD 20892 National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Privacy Act Coordinator, NIAMS, NIH Natcher Building, Room 5QS49 45 Center Drive Bethesda, MD 20892 National Institute of Child Health and Human Development (NICHD) Privacy Act Coordinator, NICHD, NIH	6100 Executive Blvd., Room 5D01 North Bethesda, MD 20892 National Institute on Deafness and Other Communication Disorders NIDCD) Privacy Act Coordinator, NIDCD, NIH Building 31, Room 3C02 9000 Rockville Pike Bethesda, MD 20892 National Institute of Dental Research (NIDR) Privacy Act Coordinator, NIDR, NIH Building 31, Room 2C-35 31 Center Drive, MSC 2290 Bethesda, MD 20892-2290 National Institute of Diabetes and Digestive and Kidney Disease NIDDK) Privacy Act Coordinator, NIDDK, NIH Building 31, Room 9A47 31 Center Drive Bethesda, MD 20892

National Institute on Drug Abuse (NIDA) Privacy Act Coordinator, NIDA, NIH Parklawn Building, Room 10A_42 5600 Fishers Lane Rockville, Maryland 20857 National Institute of Environmental Health Sciences (NIEHS) Chief, Epidemiology Branch, NIEHS, NIH P.O. Box 12233 Research Triangle Park North Carolina 27709	National Institute of Mental Health (NIMH) Privacy Act Coordinator, NIMH, NIH Parklawn Building, Room 7C-22 5600 Fishers Lane Rockville, Maryland 20857 National Institute of Neurological Disorders and Stroke (NINDS) Privacy Act Coordinator, NINDS, NIH Federal Building, Room 816 7550 Wisconsin Avenue Bethesda, MD 20892	National Center for Human Genome Research (NCHGR) Chief, Office of Human Genome Communications NGHGR, NIH Building 38A, Room 617 9000 Rockville Pike Bethesda, Maryland 20892

RECORD ACCESS PROCEDURE:
Same as notification procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:
Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES: The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: Referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT: None.

Appendix I: System Managers and Addresses

Office of the Director, NIH Associate Director for Disease Prevention, OD, NIH Building 1, Room 260 1 Center Drive Bethesda, MD 20892 National Cancer Institute Computer Systems Analyst, DCBD, NCI, NIH Executive Plaza North, Room 344 Bethesda, MD 20892 American Burkitt's Lymphoma Registry Division of Cancer Etiology, NCI, NIH Executive Plaza North, Suite 434 6130 Executive Blvd. Bethesda, MD 20892	Chief, Genetic Epidemiology Branch, EBP, DCE, NCI, NIH Executive Plaza North, Suite 439 6130 Executive Blvd. Bethesda, MD 20892 Chief, Clinical Genetics Section Clinical Epidemiology Branch, DCE, NCI, NIH Executive Plaza North, Suite 400 6130 Executive Blvd. Bethesda, MD 20892 Program Director, Research Resources Biological Carcinogenesis Branch, DCE, NCI, NIH Executive Plaza North, Room 540 6130 Executive Blvd. Bethesda, MD 20892	Chief, Environmental Epidemiology Branch, DCE, NCI, NIH Executive Plaza North, Room 443 6130 Executive Blvd. Bethesda, MD 20892 Associate Director, Surveillance Program, DCPC, NCI, NIH Executive Plaza North, Room 343K 6130 Executive Blvd. Bethesda, MD 20892 Head, Biostatistics and Data Management Section, DCT, NCI, NIH 8601 Old Georgetown Road Bethesda, MD 20892

Chief, Clinical Research Branch
Biological Response Modifiers
Program Frederick Cancer Research
and Development Center, DCT, NCI,
NIH 501 W. 7th Street, Suite #3
Frederick, MD 21701

Deputy Branch Chief, Navy Hospital
NCI--Naval Medical Oncology
Branch,
DCT, NCI, NIH
Building 8, Room 5101
Bethesda, MD 20814

Chief, Pharmaceutical Management
Branch Cancer Therapy Evaluation
Program, DCT, NCI, NIH
Executive Plaza North, Suite 804
Bethesda, MD 20892

Director, Extramural Clinical Studies,
BRB, BRMP, DCT, NCI, NIH
Frederick Cancer Research and
Development Center Fort Detrick
Frederick, MD 21701

National Eye Institute
Clinical Director, NEI, NIH
Building 10, Room 10N_202
10 Center Drive
Bethesda, MD 20892

Director, Division of Biometry and
Epidemiology, NEI, NIH Building 31,
Room 6A-52
31 Center Drive
Bethesda, MD 20892

National Heart Lung and Blood
Institute Administrative Officer,
Division of Intramural Research,
NHLBI, NIH Building 10 Room
7N220
10 Center Drive, MSC 1670
Bethesda, MD 20892-1670

Senior Scientific Advisor, OD
Division of Epidemiology and
Clinical Applications, NHLBI, NIH
Federal Building, 220
7550 Wisconsin Avenue
Bethesda, MD 20892

National Institute on Aging
Computer Scientist, Longitudinal Studies
Branch, IRP, NIH
Gerontology Research Center, GRC
4940 Eastern Avenue
Baltimore, MD 21224

Associate Director, Epidemiology,
Demography and Biometry Program,
NIA, NIH
Gateway Building, Suite 3C309 7201
Wisconsin Avenue
Bethesda, MD 20892

National Institute on Alcohol Abuse and
Alcoholism Deputy Director, Division of
Biometry and Epidemiology, NIAAA,
NIH Willco Building, Suite 514
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

Deputy Director, Div. of Clinical and
Prevention Res., NIAAA, NIH Willco
Building, Suite 505
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

National Institute of Allergy and
Infectious Diseases Chief, Respiratory
Viruses Section, LID, NIAID, NIH
Building 7, Room 106 9000 Rockville
Pike
Bethesda, MD 20892

Chief, Hepatitis Virus Section, LID,
NIAID, NIH Building 7, Room 202 9000
Rockville Pike
Bethesda, MD 20892

Chief, Epidemology and Biometry
Branch, DMID, NIAID, NIH
Solar Building, Room 3A24 Bethesda,
Maryland 20892

Special Assistant, Clinical Research
Program, DAIDS, NIAID, NIH
Solar Building, Room 2C-20
6003 Executive Blvd.
Bethesda, MD 20892

National Institute of Arthritis and
Musculoskeletal and Skin Diseases
Clinical Director, NIAMS, NIH Building
10, Room 9S205
10 Center Drive
Bethesda, MD 20892

National Institute of Child Health and
Human Development Chief, Contracts
Management Branch, NICHD, NIH
Executive Plaza North, Room 7A07
6100 Executive Blvd. North
Bethesda, MD 20892

National Institute on Deafness and
Other Communication Disorders
Acting Director of Intramural
Research, NIDCD, NIH
Building 31, Room 3C02
31 Center Drive
Bethesda, MD 20892

Director, Division of Human
Communication, NIDCD, NIH
Executive Plaza South, Room 400B
6120 Executive Boulevard Rockville,
MD 20852

National Institute of Dental Research
Deputy Clinical Director, NIDR, NIH
Building 10,
Room 1N-113
0 Center Drive, MSC 1190 Bethesda,
MD 20892-1190

Research Psychologist, Clinical
Invsetigations, NIDR, NIH
Building 10, Room 1N114
10 Center Drive, MSC 1190 Bethesda,
MD 20892-1190

Chief, Contract Management Section
Extramural Program, NIDR, NIH
Natcher Building,
Room 4AN-44B
45 Center Drive, MSC 6402 Bethesda,
MD 20892-6402

National Institute of Diabetes and
Digestive and Kidney Diseases Chief,
Clinical Investigations,
NIDDK, NIH Building 10,
Room 9N222
10 Center Drive
Bethesda, MD 20892

Chief, Phoenix Clinical Research Section, NIDDK, NIH Phoenix Area Indian Hospital, Room 541 4212 North 16th Street Phoenix, Arizona 85016 Chief, Diabetes Research Section, DPB, DDEMD, NIDDK, NIH Natcher Building, Room 5AN-18G 45 Center Drive, MSC 6600 Bethesda, MD 20892 National Institute on Drug Abuse Privacy Act Coordinator, NIDA, NIH Parklawn Building, Room 10A_42 5600 Fishers Lane Rockville, Maryland 20857 National Institute of Environmental Health Sciences Chief, Epidemiology Branch, NIEHS, NIH P.O. Box 12233 Research Triangle Park North Carolina 27709 National Institute of Mental Health Director, Intramural Research Program, NIMH, NIH Building 10, Room 4N-224 9000 Rockville Pike Bethesda, MD 20205 Privacy Act Coordinator, NIMH, NIH Parklawn Building, Room 7C22 5600 Fishers Lane Rockville, Maryland 20857	Clinical Director, Neuroscience Research Center, DIRP, NIMH Saint Elizabeths Hospital, William A. White Building, Room 133 700 Martin Luther King Jr., Avenue, SE Washington, DC 20032 National Institute of Neurological Disorders and Stroke Chief, Epilepsy Branch, NINDS, NIH Federal Building, Room 114 7750 Wisconsin Avenue Bethesda, MD 20892 Chief, Development Neurology Branch, NINDS, NIH Federal Building, NIH 7550 Wisconsin Avenue Bethesda, MD 20892 Assistant Director, CNP, DIR, NINDS, NIH Building 10, Room 5N226 10 Center Drive Bethesda, MD 20892 Deputy Chief, Laboratory of Central Nervous Systems Studies Intramural Research Program, NINDS, NIH Building 36, Room 5B21, 9000 Rockville Pike Bethesda, MD 20892	Director, Division of Fundamental Neurosciences, NINDS, NIH Federal Building, Room 916 7550 Wisconsin Ave Bethesda, MD 20892 Director, Division of Convulsive, Developmental and Neuromuscular Disorders, NINDS, NIH Federal Building, Room 816 7550 Wisconsin Avenue Bethesda, MD 20892 Director, Division of Demyelinating Atrophic, and Dementing Disorders, NINDS, NIH Federal Building, Room 810 7550 Wisconsin Avenue Bethesda, MD 20892 Director, Division of Stroke and Trauma, NINDS, NIH Federal Building, Room 8A08 7550 Wisconsin Avenue Bethesda, MD 20892 National Center for Human Genome Research Chief, Office of Human Genome Communications, NCHGR, NIH Building 38A, Room 617 9000 Rockville Pike Bethesda, MD 20892

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:	
Total Enrollment:	**Protocol Number:**
Contract Number:	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	**Sex/Gender**			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: **Total of All Subjects***				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date Cumulative)

Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not report				
Racial Categories: Total of Hispanics or Latinos**				

*** These totals must agree** ****These totals must agree**